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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region d1842b

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 331-2909

April 14, 1998

WARNING LETTER

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

RELEASE

REVIEWED BY [signature] **C.O.** 4/14/98 **DATE**

Philip Chen, President
Takao, Inc.
1037 Rt 46 East, Suite C-208
Clifton, NJ 07013

98-NWJ-21

Dear Mr. Chen:

This letter is in reference to the promotion, marketing, and distribution of the products "Bidara", "Kitara", "Milk Thistle", and "H&V Natural Herb Formula."

Promotional literature for your products makes the following claims:

- "Bidara" claims include: "to stop bleeding, itching and swelling of internal and external hemorrhoids. Shrink and eradicate hemorrhoid tissue" and "relief constipation, anti-inflammation properties ... may prevent high blood pressure & protect heart disease ... reduces gumswelling".

- "Kitara" claims include: "for people plagued by herpes ... relieve people from painful herpes attacks and suppress it from recurrence" and "Takao is confident about the herpes-curing properties of these herbal medicinal capsules, and would like to make this herbal wonder drug available to the herpes-suffering public".

- "Milk Thistle" claims include: "to treat liver's dysfunction ... its ability to address many forms of chronic liver disease ... emergency room use for poisonings affecting the liver", "Use of Milk Thistle extract has resulted in a significant improvement in long- term survival rates of cirrhosis sufferers", and "widely used for the treatment of hepatitis A, B, and C".

- "H&V Natural Herb Formula" claims include: "anti-cancer function"; "More than 100 patients with various tumors such as lung cancer, rectum cancer, brain tumors, liver cancer, ovary cancer and leukemia ... to prolong a patient's life"; "treatment for patients with cancer and treatment for ... chronic diseases and liver diseases"; "these T cells constitute the cellular immunity of the body. It will help the body defend against harmful microbes (virus, bacteria, fungus, and parasites)"; and "cytotoxic T cell - it attacks and destroys foreign tissues and viruses".

Based on the claims made for these products and their intended uses, these products are drugs [Section 201(g) of the Food, Drug, and Cosmetics Act (the Act)]. They are new drugs [Section 201(p) of the Act] and may not be legally marketed in the United States without approved New Drug Applications (Section 505).

These drugs are also misbranded [Section 502(f)(1)] because the labeling fails to bear adequate directions for use and is false and misleading as it suggests that the products are safe and effective for their intended uses when this has not been established [Section 502(a)].

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Bldg., Third Floor, Parsippany, NJ 07054, Attention: Mercedes B. Mota, Compliance Officer.

Sincerely,

Edward H. Wilkens, for
Douglas I. Ellsworth
Director, New Jersey District